

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated October 26, 2007 (hereinafter Office Action) have been considered. Claims 1-18 and 30-36 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 are rejected based on 35 U.S.C. §102(b) as being anticipated by U.S. Re. No. 30,750 to *Diack et al.* (hereinafter "*Diack*").

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicant respectfully submits that *Diack* does not teach each and every element of independent claims 1 and 30, and therefore fails to anticipate these claims.

The Applicant's independent claims 1 and 30 each recite, among other features, some variation of detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources, receiving information associated with a non-electrophysiological cardiac source, and separating a signal from the composite electrical signal using source separation.

Diack discloses a cardiac resuscitator and monitoring apparatus. (Abstract). *Diack's* apparatus senses EKG information (Col. 17, Line 44). The Examiner identifies element 110 of Fig. 14 (element 110 being a band pass filter) and Col. 18, Line 66 as teaching detecting a composite electrical signal and separating a signal from the composite signal using source separation. The Applicant respectfully submits that *Diack's* disclosure as a whole, even in the cited portions, does not provide a teaching of source separation. The Applicant respectfully submits that *Diack* does not contemplate using source separation, and describes methods which are different from source separation methods.

One of ordinary skill in the art would understand that band pass filtering techniques are different from signal source separation techniques. Band pass filtering filters out specified lower and higher frequencies components from a signal. Band pass filtering is different than separating a specific signal from a composite signal, the signals being separated according to their sources. (See Page 26, Line 27 – Page 27, Line 4 of Applicant's Specification). Band pass filtering techniques operate by using the various frequencies in a signal while source separation techniques operate by separating signals according to their respective signal sources.

The "Response to Arguments" section of the Office Action states that:

the filter technique taught by Diack and the R-wave selector/beat separation taught by Yomtov are "source separation" because they separate desired source signal (the clean ECG signal, and an individual beat signal, respectively) from undesired sources (e.g., skeletal noise, other beats, etc.). Regardless of whether this is performed via manipulation of frequencies or time windowing, the desired source signal is separated from the noise signal. This is a separation of a signal according to its respective source origin. (Pages 4-5).

The Applicant respectfully submits that filtering one individual beat from other beats using a band pass filter as taught by *Diack* does not correspond to source separation, because the signals are from the same cardiac source.

Moreover, even if a band pass filter is able to filter low and high frequency noise out of a signal, such filtering is not conducted according to the source of the noise. A band pass filter will attempt to filter out low and high frequency noise regardless of noise origin, and will not filter out noise frequencies within the band, regardless of the source (cardiac or skeletal muscle). For example, a band pass filter will attempt to filter out high and low frequencies produced by the heart while it also attempts to filter out high and low frequencies produced by skeletal muscle. Likewise, a band pass filter will let mid frequency

skeletal muscle signals pass just as it lets mid frequency cardiac signals pass. *Diack* acknowledges this in stating that the “band pass filter 110 [is] employed to reduce the effects of muscle potentials” (Col. 19, Lines 1-2; emphasis added). Accordingly, the Applicant respectfully submits that *Diack*’s band pass filtering operates without regard to signal source, and as such does not separate according to the source of a signal component.

Therefore, the Applicant respectfully submits that *Diack* does not teach separating a signal from the composite electrical signal using source separation, as recited in independent claims 1 and 30.

The Applicant’s independent claims 1 and 30 each further recite, among other features, some variation of verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

Diack’s apparatus uses a microphone for sensing respiration sounds. (Col. 19, Lines 39-50, discussing Fig. 14, referenced by the Examiner). “The microphone is employed for ascertaining bodily movement or physical activity, and in particular for ascertaining respiration sound.” (Col. 19, Lines 44-47).

Diack’s apparatus uses both sensed EKG signals and respiration sounds to select an appropriate therapy from several therapy options. (See Table 1, as cited on Page 2 of the Office Action). Specifically, if normal respiration and EKG patterns are sensed, then no action is taken (first line of Table I); if heart activity is sensed with no respiration, then a defibrillation therapy is applied (second line of Table I); and if heart rhythm and respiration are not sensed (indicating cardiac arrest) then pacing is applied (third line of Table I). (See Col. 18, Lines 20-33).

Diack does not disclose that any of the sensed signals are used to verify another signal. Instead, as illustrated by Table I, the similarities and differences between the signals are used to trigger various therapies. The Applicant respectfully submits that considering both EKG and respiration signals in selecting a therapy does not constitute one signal validating another signal, particularly not confirming or rejecting a signal as actually being a separated cardiac signal. Accordingly, the Applicant respectfully submits that *Diack* does not teach verifying that the separated signal is a cardiac signal using the separated signal

and the non-electrophysiological cardiac source information, as recited in independent claims 1 and 30.

The “Response to Arguments” section of the Office Action states that:

regardless of whether the signals are used to verify whether the separated signals is a cardiac signal (verses non-cardiac) signal, the two signals are used to determine whether the signal is a “normal cardiac signal” (verses an abnormal cardiac signal). Since the normal and abnormal cardiac signals are examples of “a cardiac signal”, as claimed, Diack anticipates the claimed subject matter. (Page 6).

The Applicant respectfully submits that it appears that the above statement acknowledges that *Diack* just assumes that the collected EKG signal is cardiac signal and only determines whether the electrical signal represents a normal or abnormal cardiac signal. In terms of anticipating the Applicant’s claims, it is not sufficient that *Diack* distinguishes between abnormal and normal cardiac signals, as making an assumption that a signal is a cardiac signal is essentially the opposite of verifying that the signal is a cardiac signal. Without at least some teaching of a step whereby *Diack* affirmatively verifies that an electrical signal is actually a cardiac signal, *Diack* cannot anticipate at least claims 1 and 30.

As such, the Applicant respectfully submits that *Diack* does not teach verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in some variation in each of independent claims 1 and 30.

For each of the reasons discussed above, the Applicant respectfully submits that *Diack* fails to teach each and every element and limitation of at least independent claims 1 and 30, and therefore cannot anticipate these claims.

Dependent claims 4, 7, 8, 10, 16-19, 31, and 34-36, which are dependent from independent claims 1 and 30, respectively, were also rejected under 35 U.S.C. §102(b) as

being unpatentable over *Diack*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 30. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 4, 7, 8, 10, 16-19, 31, and 34-36 are also not anticipated by *Diack*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 as being anticipated by *Diack* is not sustainable, the withdrawal of which is respectfully requested.

Claims 1-19 and 30-36 are rejected based on 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,388,578 to *Yomtov et al.* (hereinafter “*Yomtov*”) in view of U.S. Publication No. 2005/0240234 by *Joo et al.* (hereinafter “*Joo*”).

The Applicant’s independent claims 1 and 30 each recite, among other features, some variation of detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources, receiving information associated with a non-electrophysiological cardiac source, and separating a signal from the composite electrical signal using source separation.

Yomtov discloses an implantable cardiac monitor. The Examiner identifies element 96 (an R wave detector), Col. 17, Line 40, and Figs. 8A-B of *Tomtov* as disclosing separating a signal from the composite signal and verifying that the separated signal is a cardiac signal using a second cardiac source signal. (Page 4).

The Applicant respectfully submits that it is unclear which methodology of *Yomtov* is being interpreted as constituting performing source separation of a composite signal. Even so, source separation is not contemplated by *Yomtov*. The Applicant refers to the above discussion concerning the understanding of source separation as a particular methodology that separates one or more signals from a composite signal, the separation being performed according to the source of the particular signal. A review of *Yomtov* fails to identify any disclosure of source separation techniques.

As illustrated in *Yomtov's* Figure 3, the electrocardiograms provided by the first and second channels of the multiplexer are used for detecting R waves and are thus coupled to the R wave detector 96. In addition, the first and second channels of the multiplexer 74 are also coupled to the pacemaker detector 94 for detecting ventricular beats initiated by a pace applied to the heart by a pacemaker. (Col. 9, Lines 14-30).

The Applicant respectfully submits that distinguishing one type of beat from another (*e.g.*, intrinsic vs. paced) does not correspond to source separation, because the ECG signals are still from the same cardiac source (the Applicant notes that the source of an ECG signal is the heart, regardless of whether from a paced or intrinsic beat). As such, the signals are not separated according to the source of the signal.

The "Response to Arguments" section of the Office Action states:

Since the signals in both channels are separated by beat, either or both channels are the "separated signal" that the claim language requires. (Page 6).

The Applicant respectfully submits that even if two of *Yomtov's* channels represent different types of heart beats, each still represents beats from the same cardiac source. As such, the channels do not carry components of a composite signal separated using source separation methodologies.

The "Response to Arguments" section of the Office Action further states that:

The R-wave detector/beat separation taught by *Yomtov* are "source separation" because they separate the desired source signal (the clean ECG signal, and an individual beat signal, respectively) from undesired sources (*e.g.*, skeletal noise, other beats, etc.). Regardless of whether this is performed via manipulation of frequencies or time windowing, the desired source signal is separated from the noise signal. This is a separation of a signal according to its respective source origin. (Pages 4-5).

With regard to time windowing and filtering, *Yomtov* states:

The microprocessor establishes an interrogation window which is wide enough to encompass the QRS complex. To determine the three fiducial points, the microprocessor 92 performs a band pass differentiating function upon the stored ECG data which eliminates the P wave and the T wave from the ECG and performs slope discrimination of the QRS complex. (Col. 14, Lines 24-31).

The Applicant respectfully submits that eliminating the P and T waves while keeping the QRS complex of an ECG signal does not constitute source separation, as both of the eliminated and preserved waves have the same common cardiac source. As such, they are not separated using source separation.

Furthermore, even if *Yomtov* discloses identifying channels containing certain beat types, it is unclear how this constitutes separating a signal from a composite electrical signal. The pacemaker detector 94 causes the microprocessor to “disregard electrocardiograms which correspond to heart activity resulting from a pacemaker stimulus.” (Col. 9, Lines 26-30; emphasis added). Even if an electrocardiogram signal is disregarded, this does not constitute separating the signal from a composite electrical signal.

Although the Examiner does not rely on the *Joo* reference to teach or suggest separating a signal from the composite electrical signal using source separation methodologies, a review of the *Joo* reference fails to identify such a teaching or suggestion. Therefore, the Applicant respectfully submits that the combination of *Yomtov* and *Joo* fails to disclose separating a signal from the composite electrical signal, as recited in independent claims 1 and 30.

The Applicant’s independent claims 1 and 30 each further recite, among other features, some variation of verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

It appears that in addressing the above claim limitations on Page 3 of the Office Action, the rejection relies on the following passage of *Yomtov* which discusses Figs. 8A and 8B:

In performing step 178 to determine if a valid beat had been detected, the microprocessor utilizes the following criteria. If both the first and second channels contained noise, the microprocessor will determine that a reliable beat classification cannot be performed. If the microprocessor detected that there was noise in one channel and was unable to verify a detected QRS complex in the other channel, it will determine that a valid beat had not been detected.

The Applicant respectfully submits that it is unclear from the passage above which of the first and second channels is considered by the Office Action to contain a signal separated from a composite signal. Even so, neither of these channels is used to verify the other channel as a separated cardiac signal. Although each channel is “verified” as containing a heart beat, *Yomtov* appears to verify each channel independently of the other using thresholds. For example, when discussing the verification methods of Figs. 8A-B, *Yomtov* states that:

if there was noise in the first channel, the microprocessor then proceeds to step 174 to verify that the data stored in the random access memory 84 and obtained from the second channel indicates that there was a valid QRS complex in the second channel. Preferably this is accomplished by discerning if the data stored in the random access memory 84 obtained from the second channel was above a given threshold. (Col. 17, Lines 10-17).

As such, *Yomtov* discloses checking beat detection of a second channel when noise is sensed in the first channel. The Applicant respectfully submits that merely switching channels because of noise does not constitute verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

Yomtov further discusses the method used in Figs. 8A-B for verifying that a heart beat was detected:

For example, the microprocessor 92 analyzes the stored data for zero crossings at times which correspond to the ST segment of the ECG wherein, if the heart beat is a valid heart beat, the data would indicate a generally constant level. However, if there was noise in the first channel, the microprocessor will detect zero crossings resulting from signals of changing directions which would not normally occur during this interval. (Col. 16, Lines 61-68).

Accordingly, *Yomtov* discloses independently verifying that data collected on a particular channel is a heart beat by tracking zero crossings and using thresholds, not using one channel to verify that the other channel comprises a cardiac signal. For at least this reason, the Applicant respectfully submits that *Yomtov* does not disclose verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in independent claims 1 and 30.

The “Response to Arguments” section of the Office Action states:

Regardless of *Yomtov*’s discussion of thresholds or channel switching at the top of column 17, the cited passage (starting at line 40 of column 17) very clearly indicates that both signals from the first and second channels are used to verify a beat is a valid heart signal. (Pages 6-7).

The cited Col. 17, Lines 40-48 of *Yomtov* states:

In performing step 178 to determine if a valid beat had been detected, the microprocessor utilizes the following criteria. If both the first and second channels contained noise, the microprocessor will determine that a reliable beat classification cannot be performed. If the microprocessor detected that there was noise in one channel and was unable to verify a detected QRS complex in the other channel, it will determine that a valid beat had not been detected. As a result, if in step 178 the microprocessor determines that a valid beat had not been detected, it will set in step 182 another refractory period of, for example, 80 milliseconds.

The Applicant respectfully submits that the above passage concerns conditions under which signals will not be verified. The actual verification is performed, as discussed above, independently for each signal using thresholds, not a different signal. (Col. 16, Lines 61-68). As such, even if Col. 17, Lines 40-48 of *Yomtov* discloses conditions under which a signal will not be verified, the claims recite verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information

Although the Examiner does not rely on the *Joo* reference to teach or suggest verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, the Applicant respectfully submits that *Joo* does not contain such a teaching or suggestion, properly combinable with the *Yomtov* reference, to render independent claims 1 and 30 obvious.

For example, even if *Joo* provides multiple independent methods to detect the presence of a cardiac pulse in the patient ([0100]), such a disclosure does not constitute verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

Each of claims 2-19 and 31-36 depend from independent claims 1 and 30, respectively. Independent claims 1 and 30 are not obvious for at least the reason that the cited references fail to teach or suggest each and every limitation recited in each claim. Even though the Examiner does not rely on the *Wells* reference to teach or suggest any limitations of independent claims 1 or 30, *Wells* does not provide any teaching or suggestion, properly combinable with the *Yomtov* and *Joo* references, to cure all of the deficiencies of the *Yomtov* and *Joo* references and render independent claims 1 and 30 obvious. Furthermore, while the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 30. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Therefore, dependent claims 2-19 and 31-36 are not made obvious by *Yomtov*, even in combination with *Joo* and further in combination with *Wells*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 1-19 and 30-36 and notification that these claims are in condition for allowance.

Claims 14 and 15 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Yomtov* in view of *Joo*, as applied to claim 1, and further in view of U.S. Publication No. 2003/0032889 by *Wells* (hereinafter "*Wells*").

Each of claims 14 and 15 depend from independent claim 1. Independent claim 1 is not obvious for at least the reason that the cited references fail to teach or suggest each and every limitation recited in each claim. Furthermore, while the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then

any claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Therefore, dependent claims 14 and 15 are not made obvious by *Yomtov*, even in combination with *Joo* and *Wells*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 14 and 15 and notification that these claims are in condition for allowance.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of the Applicant's invention, officially noticed facts, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in the future.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.606PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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